Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 1-6 are pending in this application.

Claim 16 has been canceled. Claim 1 has been amended to add language as suggested by the Examiner at office action paragraph 14.

No new matter is added by amendment. Entry of this amendment is believed to place the application in condition for allowance or in better condition for appeal. Therefore, entry of the amendment is believed proper and is respectfully requested. Applicants reserve the right to file one or more continuation applications directed to the canceled embodiments.

Miscellaneous

(1) The Withdrawal of the Previous Rejections

Applicants note, with thanks, the withdrawn of certain of the previous rejections as listed at Office Action pages 2-3.

(2) The New Objection to the Disclosure

At page 10 of the Office Action, the Examiner notes that the benefit claim to PCT Application No. PCT/US86/02269, filed October 27, 1986 (abandoned) and to U.S. Application No. 06/793,980, filed November 1, 1985 (abandoned) was canceled by

amendment. The Examiner also notes that both documents remain incorporated by reference into the instant application and the Examiner asks for clarification.

An incorporation by reference and a benefit claim are two different things. An application does not need to claim the benefit of an earlier application in order to incorporate it by reference. Therefore, it is possible to cancel the benefit claim, but yet leave the text of the indicated specification incorporated by reference into the current specification. It is the text that is incorporated by reference, not the filing date. Therefore, no correction is required and this objection may be withdrawn.

The Rejections

1. The rejection under 35 U.S.C. § 112, second paragraph

"chimeric"

At Office Action page 3, paragraph 12, claim 2 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for reciting "chimeric." Applicants respectfully traverse this rejection.

The Examiner states that the specification discloses a chimeric immunoglobulin; however, the claim is drawn to chimeric heavy and light chains and the defining structural features of the chimeric heavy and light chains are unclear. The Examiner asks if the heavy and light chains are chimeric as in a humanized antibody wherein non-human CDRs are inserted into framework regions or is the antibody/immunoglobulin chimeric such that it contains non-human variable regions fused to human constant

regions or are the heavy and light chains fused to some non-immunoglobulin molecule such that they are chimeric.

The examples provided by the Examiner are all species of chimeric immunoglobulin chains. The invention does not require that chimeric be limited to exclude any of the examples listed by the Examiner. The chains of claim 2 could be chimeric for any of the recited reasons. That the word "chimeric" may encompass more than one way in which the artisan uses the word chimeric does not make the claim indefinite when the claim can encompass each of those ways. The ability of the Examiner to enumerate specific species encompassed by the claim language shows that the metes and bounds of the claims can be easily determined. Breadth is not indefiniteness. Applicants respectfully assert that prima facie indefiniteness is not established and this rejection may be withdrawn.

Summary of the rejections under 35 U.S.C. § 112, second paragraph

Applicants respectfully assert that each and every one of the rejections under 35 U.S.C. § 112, second paragraph for enablement have been obviated by the amendments and remarks above. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

2. The rejection under 35 U.S.C. § 112, first paragraph for enablement

At Office Action page 4, paragraph 14, claims 1-6 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. Applicants respectfully traverse this rejection.

2(a) The Examiner states that the claims are drawn to a nucleic acid encoding a heavy chain immunoglobulin and fragments thereof and a light chain immunoglobulin, which are incomplete antibodies that do not contain complete heavy chain and light chain variable regions.

A complete heavy and/or light chain variable region is not required by the teachings of the specification. For example, at specification page 30, last full paragraph, it is taught that " . . . it is not necessary for the complete coding region for variable or constant regions to be present, as long as a functionally operating region is present and available." In addition, Applicants have adopted the language proposed by the Examiner in this regard. Independent claim 1 now recites that the encoded immunoglobulin or antigen binding fragment thereof binds antigen.

2(b) The Examiner states that the claims encompass molecules comprising a fragment of a heavy chain and a light chain and that the formation of an intact antigen-binding site generally requires the association of the complete heavy and light chain variable regions, each of which consists of three CDRs.

Recitation of CDR regions is not required for the artisan to make and use the claimed invention without undue experimentation.

2(c)The Examiner further states that the teachings of the specification are limited to polynucleotides encoding antibodies or immunoglobulins comprising both a heavy chain and a light chain and the antibody/immunoglobulin binds antigen. Applicants respectfully disagree. However, in the interests of furthering prosecution, Applicants have adopted language proposed by the examiner.

2(d) The Examiner relies on Rudikoff as evidence of an unpredictability in the art that even minor changes in the amino acid sequences of the variable regions, particularly the CDRs may dramatically affect antigen-binding function. The Examiner concludes that it is unlikely that antibodies/immunoglobulins comprising only a fragment of the heavy chain and a light chain as defined by the claim have antigen-binding function and the claims do not contain any functional language. Applicants respectfully disagree. However, in the interests of furthering prosecution, Applicants have amended claim 1 to insert functional language.

Summary of the rejections under 35 U.S.C. § 112, first paragraph for enablement

Applicants respectfully assert that each and every one of the rejections under 35 U.S.C. § 112, first paragraph for enablement have been obviated by the amendments and remarks above. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

3. The rejections under 35 U.S.C. § 102

Claim 16 is rejected under 35 U.S.C. § 102(b) over a series of articles, and under 35 U.S.C. 102(e) over Cabilly et al, US 4,816,567. Applicants respectfully traverse each of these rejections. However, in the interests of advancing prosecution, Applicants have canceled claim 16 without prejudice or disclaimer.

Summary of the rejections under 35 U.S.C. § 102

Applicants respectfully assert that each and every one of the rejections under 35 U.S.C. § 102(b) and (e) have been obviated by the amendments and remarks above. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding office action and, as such, the present application is in condition for allowance. If the examiner believes, for any reason, that personal communication will expedite prosecution of this application, the examiner is invited to telephone the undersigned at the number provided. Prompt and favorable consideration of this supplemental amendment and reply is respectfully requested.

Respectfully submitted,

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